DECLARATION OF DOROTA A. GREJNER-BRZEZINSKA

I, Dorota A. Grejner-Brzezinska, declare as follows:

1. I am a resident of Wisconsin and over 18 years of age. I have personal knowledge of the matters set forth in this declaration, except to those matters stated upon information and belief; as to those matters, I believe them to be true. If called as a witness, I could and would testify competently to these facts.

2. I am currently employed by the University of Wisconsin–Madison as Vice Chancellor for Research. In this role, I serve as the chief research officer for UW–Madison, overseeing the Office of the Vice Chancellor for Research, which includes the administration of 20 cross-campus research offices and centers. I am also a professor in the College of Engineering. My professional background includes over 30 years of experience in scientific research and academic leadership. I have been elected to the National Academy of Engineering and appointed to the National Science Board by the President of the United States, among other distinctions.

3. As Vice Chancellor, I am responsible for ensuring that federal research funds are appropriately managed and for supporting the faculty, staff, and students whose work depends on these funds. UW–Madison and its researchers plan projects and staffing based on the reasonable expectation that awarded grant funding will continue for the promised project period, barring any compliance issues.

4. As of March 27, 2025, I am aware of two National Institutes of Health (NIH) award termination notices related to COVID-19 research grants. The awards terminated are described in detail below. The total value of the terminated awards was approximately $15 million. Both terminations were issued “for cause” by the U.S.

Department of Health and Human Services (HHS) on the stated basis that the COVID-19 pandemic had ended, rather than due to any failure by UW–Madison to comply with the grants' terms. Indeed, each termination notice contained identical form language asserting that "the end of the pandemic provides cause to terminate COVID-related grant funds" because the funds were for pandemic purposes and were deemed "no longer necessary." Descriptions of each award and the effects of these terminations follows.

NIH Project 5R01AI158463 (Infectious Disease Research Grant)

5. In April 2020, the NIH invited applications for "Emergency Awards: Rapid Investigation of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) and Coronavirus Disease 2019 (COVID-19) (R21, R01 Clinical Trials Not Allowed)."

6. In response, the Kirchdoerfer lab at the University of Wisconsin–Madison submitted a proposal under R01 AI158463 to examine the functions of the SARS-CoV-2 polymerase complex. The stated goal was to delineate how multiple protein subunits contribute to coronavirus replication (determine how the virus's molecular machinery contributes to its ability to make copies of its genetic material) thereby providing foundational research for the development of antiviral drugs that prevent replication.

7. On August 5, 2020, the NIH issued a Notice of Award (NOA) to UW–Madison for an NIH Research Project (R01) grant entitled "Coronavirus RNA synthesis by multicomponent protein machines." A true and correct copy of this NOA is attached as Exhibit A. The award initially covered a five-year project period from August 5, 2020, to July 31, 2025. In May 2024, a mid-project extension was requested and approved, extending the grant period to July 31, 2026. The central focus of this R01 was to understand how coronaviruses replicate their genomes.

8. Total anticipated funding for the project was approximately $2.1 million.

9. Since August 2020, UW–Madison has used the grant funds in a manner fully consistent with the stated project goals and NIH requirements regarding the award. Pursuant to the grant's aims, the study team has rapidly made research results available through open access publishing and sharing of preprints and deposited structural data in public databases. Timely Research Performance Progress Reports (RPPR) have been regularly submitted in compliance with NIH policies. UW–Madison also invested in microscopy core facility upgrades specifically to support this project, demonstrating substantial reliance on the expected continuation of the award.

10. As of March 24, 2025, there was approximately $540,000 in planned funding that remained undisbursed. UW–Madison received funds under this grant on an annual basis with the next disbursement to take place in July 2025.

11. Remaining committed funds were already incorporated into departmental staffing plans and used to justify appointments of several graduate assistants for the 2025–26 academic year. The funds would have been used to support four graduate assistants, a staff intern, two student hourly employees and partial faculty salary as well as covering the use of UW–Madison core facilities. (Core facilities are shared resources that offer a range of services needed for research and are generally supported by user fees.) Research topics studied would have included the role of the SARS-CoV-2 nsp14 exonuclease in the viral RNA replication complex, a part of the virus's molecular machinery that contributes to equipping the virus with antiviral drug resistance and also would have explored roles for RNA templates in regulating polymerase function (another avenue to improve understanding of how the virus copies its genetic material).

12. On March 24, 2025, approximately 4 years and 8 months into the 6-year term, NIH abruptly and without prior notice or indication informed UW–Madison that, effective that same date, the grant was being terminated. A true and correct copy of the Grant Termination Notification is attached as Exhibit B.

13. The Grant Termination Notification states that "[t]he end of the pandemic provides cause to terminate COVID-related grant funds. These funds were issued for a limited purpose: to ameliorate the effects of the pandemic. Now that the pandemic is over, the grant funds are no longer necessary." The Notification further notes that "[t]he premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities."

14. When contacted for clarification, the NIH program officer assigned to the grant was unaware the grant had been terminated.

15. Prior to the grant award termination, NIH had never provided UW–Madison or principal investigator Robert Kirchdoerfer with notice, written or otherwise, that the grant administered by UW–Madison was in any way unsatisfactory.

16. UW–Madison and Robert Kirchdoerfer relied and acted upon the expectation and understanding that NIH would fulfill their commitment to provide the funding it had awarded to UW-Madison. The unexpected termination of award R01AI158463 significantly affects the laboratory's research operations and personnel continuity. The funding cessation impacts eight lab members and their ongoing research, impairing the Kirchdoerfer lab's ability to carry out research into mechanisms of coronavirus replication. This includes limiting or shutting down ongoing projects exploring mechanisms of viral drug resistance and regulation of viral machines. The abrupt

termination leaves 16 months of planned research incomplete, including critical experiments on antiviral drug resistance mechanisms.

17. The termination will cause significant harm by prematurely ending essential coronavirus research, squandering prior investments, disrupting scientific careers, and undermining UW–Madison's capacity to drive critical public health advancements. While we are no longer in a declared public health emergency, the SARS-CoV-2 virus and its variants continue to adversely affect the health and lives of Americans, making ongoing research crucial for public health experts. Coronaviruses have been responsible for multiple pandemics in recent decades, underscoring the importance of this research in protecting American lives and supporting our national economy.

NIH Project 1P01AI165077-01
(PanCorVac – Center for Pan-Coronavirus Vaccine Development)

18. On December 9, 2019, the National Institute of Allergy and Infectious Diseases (NIAID), part of the NIH, issued a special call for comprehensive "pan-coronavirus" vaccine research centers, recognizing the need to develop vaccines capable of protecting against multiple coronavirus types and potential future variants. This initiative, announced as an Emergency Awards Program through a Notice of Special Interest, specifically invited program project (P01) grant applications for pan-coronavirus vaccine development.

19. On September 16, 2021, the NIH issued a Notice of Award to UW–Madison for Grant No. 1P01AI165077-01, funding the establishment of the "PanCorVac" Center for Pan-Coronavirus Vaccine Development. The initial funding and terms for this center

were detailed in the corresponding Notice of Award, a true and correct copy of which is attached as Exhibit D.

20. The grant was awarded with an anticipated 5-year project period, subject to annual non-competing continuation. According to the grant proposal and award, the mission of UW–Madison's PanCorVac Center was to generate and evaluate protein-based vaccine candidates aimed not only at SARS-CoV-2 variants, but also at other coronaviruses with pandemic potential.

21. Total anticipated funding for the project was approximately $11.7 million.

22. Since 2021, UW–Madison has utilized the award funds in full accordance with both NIH's requirements regarding the nature of the grant and UW–Madison's grant application.

23. The PanCorVac Center has made substantial progress, including multiple peer-reviewed publications that demonstrated the successful development of protein-based vaccine candidates (as alternatives to mRNA-based vaccines). These candidates showed strong, broadly protective immune responses in initial animal studies. Deliverables completed prior to termination included: several vaccine candidates tested in small animal models, one peer-reviewed publication, and ongoing preclinical data analysis intended to support future follow-up studies to translate basic research into human health benefit. UW–Madison has also issued subawards to four subrecipient institutions, each of which had research personnel engaged in core PanCorVac projects.

24. As of March 24, 2025, roughly $2.5 million of planned funding remained undisbursed.

25. On March 24, 2025, approximately 3.5 years into the 5-year term, NIH issued a Revised Notice of Award terminating the grant, a true and correct copy of which is attached hereto as Exhibit D.

26. As grounds for the termination, the Revised Notice of Award cites 2 C.F.R. § 200.340 as purportedly implemented in NIH Grant Policy Statement Section 8.5.2. and contends that, "[t]hese grant funds were issued for a limited purpose: to ameliorate the effects of the pandemic. Now that the pandemic is over, the grant funds are no longer necessary. Therefore, this project is terminated."

27. UW–Madison received no prior notice, warnings, or indications of any concerns or dissatisfaction with the progress or direction of the research from NIH. Prior performance reports submitted annually were consistently approved.

28. The sudden termination will significantly impact the laboratory's research operations, personnel stability, and infrastructure investments made by UW–Madison specifically for developing medical countermeasures against respiratory viruses including influenza viruses and coronaviruses at the specialized containment laboratory space at the Influenza Research Institute. This facility, having expanded capacity to accommodate PanCorVac research, now faces reduced staffing levels, operational inefficiencies, and potential long-term impacts on its ability to support pandemic-related research. Ongoing experiments, notably advanced animal vaccine challenge studies scheduled to assess protective efficacy (how well vaccine candidates protect research subjects from infection, illness and death), have been halted abruptly, rendering previously collected data unusable in future experiments and necessitating the euthanasia of sets of experimental animals. UW–Madison and its subrecipients had made programmatic and staffing commitments in

reliance on the final phase of the project being funded as anticipated in 2025 and 2026. In light of the termination, layoff procedures have been initiated, and the UW-Madison will be instructing subrecipient institutions to stop work.

29. UW–Madison provided cost-sharing through faculty effort and dedicated high-containment lab space at the Influenza Research Institute, which will now face underutilization. Infrastructure upgrades were made with the expectation that PanCorVac research would continue through the full five-year term.

30. The termination will cause substantial harm by abruptly halting important public health research, wasting significant investments already made, diminishing the university's ability to address future coronavirus threats, and negatively impacting public health preparedness.

I declare under penalty of perjury under the laws of the United States that, to the best of my knowledge, the foregoing is true and correct.

Executed on March 28, 2025, at Madison, Wisconsin.

Dorota A. Grejner-Brzezinska,
Vice Chancellor for Research

WI Decl. of Grejner-Brzezinska, Ex. A – 3.28.2025

Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

Federal Award Date: 08/05/2020

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Grant Number: 1R01AI158463-01
FAIN: R01AI158463

Principal Investigator(s):
Robert Nicholas Kirchdoerfer, PHD

Project Title: Coronavirus RNA synthesis by multicomponent protein machines

EGAN, BRENDA A
Managing Officer
21 N. Park Street, Suite 6401
Madison, WI 537151218

Award e-mailed to: NIH@rsp.wisc.edu

Period Of Performance:
Budget Period: 08/05/2020 – 07/31/2021
Project Period: 08/05/2020 – 07/31/2025

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of $437,931 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF WISCONSIN-MADISON in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of Allergy And Infectious Diseases of the National Institutes of Health under Award Number R01AI158463. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please contact the individual(s) referenced in Section IV.

Sincerely yours,

Ann W. Devine
Grants Management Officer
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Additional information follows

SECTION I - AWARD DATA – 1R01AI158463-01

Award Calculation (U.S. Dollars)

Federal Direct Costs	$304,471
Federal F&A Costs	$133,460
Approved Budget	$437,931
Total Amount of Federal Funds Obligated (Federal Share)	$437,931
TOTAL FEDERAL AWARD AMOUNT	$437,931
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$437,931

SUMMARY TOTALS FOR ALL YEARS		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$437,931	$437,931
2	$455,907	$455,907
3	$455,907	$455,907
4	$389,042	$389,042
5	$389,042	$389,042

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

CFDA Name:	Allergy and Infectious Diseases Research
CFDA Number:	93.855
EIN:	1396006492A1
Document Number:	RAI158463ACV
PMS Account Type:	P (Subaccount)
Fiscal Year:	2020

IC	CAN	2020	2021	2022	2023	2024
AI	8044355	$437,931	$455,907	$455,907	$389,042	$389,042

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: M51C B / **OC**: 41021 / **Released**: ADEVINE 08/05/2020
Award Processed: 08/06/2020 12:15:50 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1R01AI158463-01

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – TERMS AND CONDITIONS – 1R01AI158463-01

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VI Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01AI158463. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

THIS AWARD CONTAINS GRANT SPECIFIC RESTRICTIONS. THESE RESTRICTIONS MAY ONLY BE LIFTED BY A REVISED NOTICE OF AWARD.

The budget period anniversary start date for future year(s) will be **August** 1.

****
This award provides funds to prevent, prepare for, and respond to coronavirus, domestically or internationally. These funds are restricted for the emergency response to COVID-19 only and may not be rebudgeted or used for any other purpose without (**NIAID**) prior approval.

****
A recipient may, at its own risk and without NIH prior approval incur obligations and expenditures to cover costs from January 20, 2020 (the beginning of the HHS declared Public Health Emergency), and up to the beginning date of this award if such costs are necessary to conduct the project, and would be allowable under the grant, if awarded, without NIH prior approval.

If specific expenditures would otherwise require prior approval, the recipient must obtain NIH approval before incurring the cost. NIH prior approval is required for any costs incurred prior to January 20, 2020.

All remaining pre-award cost requirements remain consistent with the NIH Grants Policy Statement (see section 7.9.1).

****
In accordance with the NIAID Financial Management Plan, NIAID does not provide funds for inflationary increases. Committed future year (s) funding was adjusted accordingly. See: https://www.niaid.nih.gov/grants-contracts/financial-management-plan.

****
Select Agents:
Awardee of a project that at any time involves a restricted experiment with a select agent, is responsible for notifying and receiving prior approval from the NIAID. Please be advised that changes in the use of a Select Agent will be considered a change in scope and require NIH awarding office prior approval. The approval is necessary for new select agent experiments as well as changes in on-going experiments that would require change in the biosafety plan and/or biosafety containment level. An approval to conduct a restricted experiment granted to an individual cannot be assumed an approval to other individuals who conduct the same restricted experiment as defined in the Select Agents Regulation 42 CFR Part 73, Section 13.b (http://www.selectagents.gov/Regulations.html).

Highly Pathogenic Agent:
NIAID defines a Highly Pathogenic Agent as an infectious Agent or Toxin that may warrant a biocontainment safety level of BSL3 or higher according to the current edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) (http://www.cdc.gov/OD/ohs/biosfty/bmbl5/bmbl5toc.htm). Research funded under this grant must adhere to the BMBL, including using the BMBL-recommended biocontainment level at a minimum. If your Institutional Biosafety Committee (or equivalent body) or designated institutional biosafety official recommend a higher biocontainment level, the highest recommended containment level must be used.
When submitting future Progress Reports indicate at the beginning of the report:

If no research with a Highly Pathogenic Agent or Select Agent has been performed or is planned to be performed under this grant.

If your IBC or equivalent body or official has determined, for example, by conducting a risk assessment, that the work being planned or performed under this grant may be conducted at a biocontainment safety level that is lower than BSL3.

If the work involves Select Agents and/or Highly Pathogenic Agents, also address the following points:

Any changes in the use of the Agent(s) or Toxin(s) including its restricted experiments that have resulted in a change in the required biocontainment level, and any resultant change in location, if applicable, as determined by your IBC or equivalent body or official.

If work with a new or additional Agent(s)/Toxin(s) is proposed in the upcoming project period, provide:

- A list of the new and/or additional Agent(s) that will be studied;
- A description of the work that will be done with the Agent(s), and whether or not the work is a restricted experiment;
- The title and location for each biocontainment resource/facility, including the name of the organization that operates the facility, and the biocontainment level at which the work will be conducted, with documentation of approval by your IBC or equivalent body or official. It is important to note if the work is being done in a new location.

STAFF CONTACTS

The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These individuals work together in overall project administration. Prior approval requests (signed by an Authorized Organizational Representative) should be submitted in writing to the Grants Management Specialist. Requests may be made via e-mail.

Grants Management Specialist: Shaun W Gratton
Email: Shaun.Gratton@nih.gov **Phone**: 240-627-3594 **Fax**: 301-493-0597

Program Official: Erik J. Stemmy
Email: erik.stemmy@nih.gov **Phone**: 240-627-3380

SPREADSHEET SUMMARY
GRANT NUMBER: 1R01AI158463-01

INSTITUTION: UNIVERSITY OF WISCONSIN-MADISON

Facilities and Administrative Costs	Year 1	Year 2	Year 3	Year 4	Year 5
F&A Cost Rate 1	55%	55.5%	55.5%	55.5%	55.5%
F&A Cost Base 1	$222,265	$285,471	$285,471	$242,471	$242,471
F&A Costs 1	$122,246	$158,436	$158,436	$134,571	$134,571
F&A Cost Rate 2	55.5%				
F&A Cost Base 2	$20,206				
F&A Costs 2	$11,214				

WI Decl. of Grejner-Brzezinska, Ex. B – 3.28.2025

Outlook

Grant Termination Notification

From Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>
Date Mon 3/24/2025 2:51 PM
To Nick Novak <nick.novak@wisc.edu>

3/24/2025

Nick Novak
University Of Wisconsin-Madison
nick.novak@wisc.edu

Dear Nick Novak:

Effective with the date of this letter, funding for Project Number 5R01AI158463-04 is hereby terminated pursuant to the Fiscal Year 2023 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2023 Policy Statement applies to your project because NIH approved your grant on 8/1/2023, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2023 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

The end of the pandemic provides cause to terminate COVID-related grant funds. These grant funds were issued for a limited purpose: to ameliorate the effects of the pandemic. Now that the pandemic is over, the grant funds are no longer necessary.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.*[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S

Michelle G. Bulls, on behalf of Emily Linde, Chief Grants Management Officer, NIAID
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] NIH Grants Policy Statement at IIA-1.
[5] *Id.* at IIA-155.
[6] NIH Grants Policy Statement at IIA-156.
[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)

[12] 12 *Id.* § 50.406(b)

WI Decl. of Grejner-Brzezinska, Ex. C – 3.28.2025

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Notice of Award
FAIN# P01AI165077
Federal Award Date
09/16/2021

Recipient Information

1. Recipient Name
UNIVERSITY OF WISCONSIN SYSTEM
21 N PARK ST STE 6401

MADISON, WI 53715

2. Congressional District of Recipient
02

3. Payment System Identifier (ID)
1396006492A1

4. Employer Identification Number (EIN)
396006492

5. Data Universal Numbering System (DUNS)
161202122

6. Recipient's Unique Entity Identifier

7. Project Director or Principal Investigator
YOSHIHIRO KAWAOKA, DVM
Professor
yoshihiro.kawaoka@wisc.edu
608-265-4925

8. Authorized Official
Brenda Egan
nih@rsp.wisc.edu
608-262-3822

Federal Agency Information

9. Awarding Agency Contact Information
Elizabeth R. Sihombing
Grants Management Specialist
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
elizabeth.sihombing@nih.gov
240-669-5530

10. Program Official Contact Information
Erik J. Stemmy
Program Officer
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
erik.stemmy@nih.gov
240-627-3380

Federal Award Information

11. Award Number
1P01AI165077-01

12. Unique Federal Award Identification Number (FAIN)
P01AI165077

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
PanCorVac (Center for Pan-Coronavirus Vaccine Development)

15. Assistance Listing Number
93.855

16. Assistance Listing Program Title
Allergy and Infectious Diseases Research

17. Award Action Type
New Competing

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information

19. Budget Period Start Date 09/16/2021 **– End Date** 08/31/2024	
20. Total Amount of Federal Funds Obligated by this Action	$7,000,324
20 a. Direct Cost Amount	$6,170,370
20 b. Indirect Cost Amount	$829,954
21. Authorized Carryover	$0
22. Offset	$0
23. Total Amount of Federal Funds Obligated this budget period	$7,000,324
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$7,000,324
26. Project Period Start Date 09/16/2021 **– End Date** 08/31/2024	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$7,000,324

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Jordan A. Kindbom

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

RESEARCH PROGRAM PROJECT
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

SECTION I – AWARD DATA – 1P01AI165077-01

Principal Investigator(s):
YOSHIHIRO KAWAOKA, DVM

Award e-mailed to: NIH@rsp.wisc.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $7,000,324 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF WISCONSIN-MADISON in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of Allergy And Infectious Diseases of the National Institutes of Health under Award Number P01AI165077. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Jordan A. Kindbom
Grants Management Officer
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	$653,967
Fringe Benefits	$221,196
Personnel Costs (Subtotal)	$878,163
Consultant Services	$60,000
Equipment	$23,942
Materials & Supplies	$311,000
Travel	$59,250
Other	$100,000
Subawards/Consortium/Contractual Costs	$4,726,015
Publication Costs	$12,000
Federal Direct Costs	$6,170,370
Federal F&A Costs	$829,954
Approved Budget	$7,000,324
Total Amount of Federal Funds Authorized (Federal Share)	$7,000,324
TOTAL FEDERAL AWARD AMOUNT	$7,000,324
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$7,000,324

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$7,000,324	$7,000,324

Fiscal Information:

Payment System Identifier:	1396006492A1
Document Number:	PAI165077AC6
PMS Account Type:	P (Subaccount)
Fiscal Year:	2021

IC	CAN	2021
AI	8050485	$7,000,324

NIH Administrative Data:
PCC: M51C S / **OC**: 41021 / **Released**: Kindbom, Jordan 09/16/2021
Award Processed: 09/17/2021 12:24:26 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1P01AI165077-01

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 1P01AI165077-01

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

MULTI-YEAR FUNDED AWARD: This is a multi-year funded award. A progress report is due annually on or before the anniversary of the budget/project period start date of the award, in accord with the instructions posted at: http://grants.nih.gov/grants/policy/myf.htm.

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) P01AI165077. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy.htm#gps.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the eRA Commons (Commons) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, http://grants.nih.gov/grants/policy/policy.htm#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) quarterly cash transaction data. A final quarterly federal cash transaction report is not required for awards in PMS B subaccounts (i.e., awards to foreign entities and to Federal agencies). NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures or quarterly federal cash transaction reporting. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level. If the grantee submits a final expenditure FFR but does not reconcile any discrepancies between expenditures

reported on the final expenditure FFR and the Final Cash Report in PMS. NIH will close the award at the lower amount. This could be considered a debt or result in disallowed costs.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: http://grants.nih.gov/grants/forms.htm. This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience*.

NIH strongly encourages electronic submission of the final invention statement through the Closeout feature in the Commons, but will accept an email or hard copy submission as indicated below.

Email: The final invention statement may be e-mailed as PDF attachments to: NIHCloseoutCenter@mail.nih.gov.

Hard copy: Paper submissions of the final invention statement may be faxed to the NIH Division of Central Grants Processing, Grants Closeout Center, at 301-480-2304, or mailed to:

National Institutes of Health
Office of Extramural Research
Division of Central Grants Processing
Grants Closeout Center
6705 Rockledge Drive
Suite 5016, MSC 7986
Bethesda, MD 20892-7986 (for regular or U.S. Postal Service Express mail)
Bethesda, MD 20817 (for other courier/express deliveries only)

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and should be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:

Additional Costs

Clinical Trial Indicator: No

This award does not support any NIH-defined Clinical Trial. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

THIS AWARD CONTAINS GRANT SPECIFIC RESTRICTIONS. THESE RESTRICTIONS MAY ONLY BE LIFTED BY A REVISED NOTICE OF AWARD.

This award provides funds to prevent, prepare for, and respond to coronavirus, domestically or internationally. These funds are restricted for the emergency response to COVID-19 only and may not be rebudgeted or used for any other purpose without NIAID prior approval.

The budget period anniversary start date for future year(s) will be **September 1.**

TRANSITION APPLICATION: In year three, an extension application may be funded following submission of a Non-competing Continuation Progress Report form. Recipients should follow the instructions for the PHS 2590 found at https://grants.nih.gov/grants/funding/2590/2590.htm ;to complete the form. All applicable sections must be completed.

The extension application must be emailed to vandhana.khurana@nih.gov by the Authorized Signing Official by 07/01/2024. An Administrative review will be conducted prior to issuing a Type 4 award for years four and five of the project period. Funding for the extension application will be contingent upon 1) assessment of the progress report, 2) review and approval of other documents necessary for continuation; and 3) availability of funds. If the extension request is not approved, the awardee will be advised of the decision in writing.

This Notice of Award (NoA) includes funds for activity with **Georgia Tech Research Corporation** in the amount of **$1,404,775** (**$887,974** direct costs + **$516,801** F&A costs).

This Notice of Award (NoA) includes funds for activity with **University of Chicago** in the amount of **$984,000** (**$600,000** direct costs + **$384,000** F&A costs).

This Notice of Award (NoA) includes funds for activity with **St. Jude Children's Research Hospital** in the amount of **$1,364,994** (**$749,997** direct costs + **$614,997** F&A costs).

This Notice of Award (NoA) includes funds for activity with **Weill Medical College of Cornell University** in the amount of **$972,246** (**$573,597** direct costs + **$398,649** F&A costs).

In accordance with the NIAID Financial Management Plan, NIAID does not provide funds for inflationary increases. Committed future year (s) funding was adjusted accordingly. See: https://www.niaid.nih.gov/grants-contracts/financial-management-plan

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This award includes human subject research studies and must conform to the DHHS policies for the Protection of Human Subjects research, which are a term and condition of award. Human subjects research is covered by the 2018 Common Rule, and may not be initiated until the associated protocols have received IRB approval as specified in 45 CFR 46. Failure to comply with the terms and conditions of award may result in the disallowance of costs and/or additional enforcement actions as outlined in Section 8.5 of the NIH Grants Policy Statement.

Awardees who conduct research involving Select Agents (see 42 CFR 73 for the Select Agent list; and 7 CFR 331 and 9 CFR 121 for the relevant animal and plant pathogens at http://www.selectagents.gov/Regulations.html) must complete registration with CDC (or APHIS, depending on the agent) before using NIH funds. No funds can be used for research involving Select Agents if the final registration certificate is denied.

Prior to conducting a restricted experiment with a Select Agent or Toxin, awardee must notify the NIAID and must request and receive approval from CDC or APHIS.

Dissemination of study data will be in accord with the Recipient's accepted genomic data sharing plan as stated in the **Just-In-Time**. Failure to adhere to the sharing plan as mutually agreed upon by the Recipient and the NIAID may result in Enforcement Actions as described in the NIH Grants Policy Statement.

The Research Performance Progress Report (RPPR), Section G.9 (Foreign component), includes reporting requirements for all research performed outside of the United States. Research conducted at the following site(s) must be reported in your RPPR:

BEN-GURION UNIVERSITY OF THE NEGEV, ISRAEL

Duke-NUS Medical School, SINGAPORE

This award is subject to the Clinical Terms of Award referenced in the NIH Guide for Grants and Contracts, July 8, 2002, NOT AI-02-032. These terms and conditions are hereby incorporated by reference, and can be accessed via the following World Wide Web address: https://www.niaid.nih.gov/grants-contracts/niaid-clinical-terms-award All submissions required by the NIAID Clinical Terms of Award must be forwarded electronically or by mail to the responsible NIAID Program Official identified on this Notice of Award.

Select Agents:
Awardee of a project that at any time involves a restricted experiment with a select agent, is responsible for notifying and receiving prior approval from the NIAID. Please be advised that changes in the use of a Select Agent will be considered a change in scope and require NIH awarding office prior approval. The approval is necessary for new select agent experiments as well as changes in on-going experiments that would require change in the biosafety plan and/or biosafety containment level. An approval to conduct a restricted experiment granted to an individual cannot be assumed an approval to other individuals who conduct the same restricted experiment as defined in the Select Agents Regulation 42 CFR Part 73, Section 13.b (http://www.selectagents.gov/Regulations.html).

Highly Pathogenic Agent:
NIAID defines a Highly Pathogenic Agent as an infectious Agent or Toxin that may warrant a biocontainment safety level of BSL3 or higher according to the current edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) (http://www.cdc.gov/OD/ohs/biosfty/bmbl5/bmbl5toc.htm). Research funded under this grant must adhere to the BMBL, including using the BMBL-recommended biocontainment level at a minimum. If your Institutional Biosafety Committee (or equivalent body) or designated institutional biosafety official recommend a higher biocontainment level, the highest recommended containment level must be used.
When submitting future Progress Reports indicate at the beginning of the report:

If no research with a Highly Pathogenic Agent or Select Agent has been performed or is planned to be performed under this grant.

If your IBC or equivalent body or official has determined, for example, by conducting a risk assessment, that the work being planned or performed under this grant may be conducted at a biocontainment safety level that is lower than BSL3.

If the work involves Select Agents and/or Highly Pathogenic Agents, also address the following points:

Any changes in the use of the Agent(s) or Toxin(s) including its restricted experiments that have resulted in a change in the required biocontainment level,

and any resultant change in location, if applicable, as determined by your IBC or equivalent body or official.

If work with a new or additional Agent(s)/Toxin(s) is proposed in the upcoming project period, provide:

- A list of the new and/or additional Agent(s) that will be studied;
- A description of the work that will be done with the Agent(s), and whether or not the work is a restricted experiment;
- The title and location for each biocontainment resource/facility, including the name of the organization that operates the facility, and the biocontainment level at which the work will be conducted, with documentation of approval by your IBC or equivalent body or official. It is important to note if the work is being done in a new location.

SPREADSHEET SUMMARY
AWARD NUMBER: 1P01AI165077-01

INSTITUTION: UNIVERSITY OF WISCONSIN-MADISON

Budget	Year 1
Salaries and Wages	$656,967
Fringe Benefits	$221,196
Personnel Costs (Subtotal)	$878,163
Consultant Services	$60,000
Equipment	$23,942
Materials & Supplies	$311,000
Travel	$59,250
Other	$100,000
Subawards/Consortium/Contractual Costs	$4,726,015
Publication Costs	$12,000
TOTAL FEDERAL DC	$6,170,370
TOTAL FEDERAL F&A	$829,954
TOTAL COST	$7,000,324

Facilities and Administrative Costs	Year 1
F&A Cost Rate 1	55.5%
F&A Cost Base 1	$540,971
F&A Costs 1	$300,239
F&A Cost Rate 2	55.5%
F&A Cost Base 2	$471,971
F&A Costs 2	$261,944
F&A Cost Rate 3	55.5%
F&A Cost Base 3	$482,471
F&A Costs 3	$267,771

WI Decl. of Grejner-Brzezinska, Ex. D – 3.28.2025

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Notice of Award
FAIN# P01AI165077
Federal Award Date
03/25/2025

Recipient Information

1. Recipient Name
UNIVERSITY OF WISCONSIN SYSTEM
21 N PARK ST STE 6301
MADISON, WI 53715

2. Congressional District of Recipient
02

3. Payment System Identifier (ID)
1396006492A1

4. Employer Identification Number (EIN)
396006492

5. Data Universal Numbering System (DUNS)
161202122

6. Recipient's Unique Entity Identifier
LCLSJAGTNZQ7

7. Project Director or Principal Investigator
YOSHIHIRO KAWAOKA, DVM
Professor
yoshihiro.kawaoka@wisc.edu
608-265-4925

8. Authorized Official
Brenda Egan
nih@rsp.wisc.edu
608-262-3822

Federal Agency Information

9. Awarding Agency Contact Information
Elizabeth R. Sihombing
Grants Management Specialist
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
elizabeth.sihombing@nih.gov
240-669-5530

10. Program Official Contact Information
JENNIFER L. Gordon
Program Officer
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
jennifer.gordon2@nih.gov
3017616805

Federal Award Information

11. Award Number
1P01AI165077-01

12. Unique Federal Award Identification Number (FAIN)
P01AI165077

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
PanCorVac (Center for Pan-Coronavirus Vaccine Development)

15. Assistance Listing Number
93.855

16. Assistance Listing Program Title
Allergy and Infectious Diseases Research

17. Award Action Type
New Competing (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 09/16/2021 **– End Date** 03/24/2025	
20. Total Amount of Federal Funds Obligated by this Action	$0
20 a. Direct Cost Amount	$0
20 b. Indirect Cost Amount	$0
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$7,000,324
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$7,000,324
26. Project Period Start Date 09/16/2021 **– End Date** 03/24/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$7,000,324

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Emily Linde

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Notice of Award

RESEARCH PROGRAM PROJECT
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

SECTION I – AWARD DATA – 1P01AI165077-01 REVISED

Principal Investigator(s):
YOSHIHIRO KAWAOKA, DVM

Award e-mailed to: NIH@rsp.wisc.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF WISCONSIN-MADISON in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of Allergy And Infectious Diseases of the National Institutes of Health under Award Number P01AI165077. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Emily Linde
Grants Management Officer
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	$656,967
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Federal Direct Costs	$6,170,370
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Approved Budget	$7,000,324
Total Amount of Federal Funds Authorized (Federal Share)	$7,000,324
TOTAL FEDERAL AWARD AMOUNT	$7,000,324
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$7,000,324	$7,000,324

Fiscal Information:

Payment System Identifier:	1396006492A1
Document Number:	PAI165077AC6
PMS Account Type:	P (Subaccount)
Fiscal Year:	2021

IC	CAN	2021
AI	8050485	$7,000,324

NIH Administrative Data:
PCC: M51Q S / **OC**: 41021 / **Released**: 03/25/2025
Award Processed: 03/26/2025 12:01:13 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1P01AI165077-01 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 1P01AI165077-01 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

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Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH

awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

Carry over of an unobligated balance into the next budget period requires Grants Management Officer prior approval.

MULTI-YEAR FUNDED AWARD: This is a multi-year funded award. A progress report is due annually on or before the anniversary of the budget/project period start date of the award, in accord with the instructions posted at: http://grants.nih.gov/grants/policy/myf.htm.

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) P01AI165077. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy.htm#gps.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the Payment Management System (PMS) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, http://grants.nih.gov/grants/policy/policy.htm#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the real-time cash drawdown data in PMS. NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: http://grants.nih.gov/grants/forms.htm. This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience*.

NIH requires electronic submission of the final invention statement through the Closeout feature in the Commons.

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and must be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – AI SPECIFIC AWARD CONDITIONS – 1P01AI165077-01 REVISED

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

REVISED AWARD: The end of the pandemic provides cause to terminate COVID-related grant funds. These grant funds were issued for a limited purpose: to ameliorate the effects of the pandemic. Now that the pandemic is over, the grant funds are no longer necessary. Therefore, this project is terminated.

Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), as applicable within 120 days of the end of this grant.

NIH is taking this enforcement action in accordance with 2 C.F.R. § 200.340 as implemented in NIH GPS Section 8.5.2. This revised award represents the final decision of the NIH. It shall be the final decision of the Department of Health and Human Services (HHS) unless within 30 days after receiving this decision you mail or email a written notice of appeal to Dr. Matthew Memoli. Please include a copy of this decision, your appeal justification, total amount in dispute, and any material or documentation that will support your position. Finally, the appeal must be signed by the institutional official authorized to sign award applications and must be dated no later than 30 days after the date of this notice.

Supersedes previous Notice of Award dated **08/30/2024**. All other terms and conditions still apply to this award.

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REVISED AWARD: This revised Notice of Award (NoA) is issued to extend the project period end date in accordance with the letter dated **07/30/2024**. The recipient is responsible for ensuring that all necessary human subjects and/or vertebrate animal requirements are fulfilled during the extension period. Failure to comply with this requirement can result in suspension and/or termination of this award, withholding of support, cost disallowances, and/or other appropriate action.

This is the final extension that will be allowed for this project.

Supersedes previous Notice of Award dated **05/26/2023**. All other terms and conditions still apply to this award.

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THIS AWARD CONTAINS GRANT SPECIFIC RESTRICTIONS. THESE RESTRICTIONS MAY ONLY BE LIFTED BY A REVISED NOTICE OF AWARD.

REVISED AWARD: This award is revised to remove the requirement to submit an extension application for years four and five of the project period.

This Notice of Award removes carryover authority on this award.

Supersedes previous Notice of Award dated 09/17/2021. All other terms and conditions still apply to this award.

This award provides funds to prevent, prepare for, and respond to coronavirus, domestically or internationally. These funds are restricted for the emergency response to COVID-19 only and may not be rebudgeted or used for any other purpose without NIAID prior approval.

The budget period anniversary start date for future year(s) will be **September 1.**

This Notice of Award (NoA) includes funds for activity with **Georgia Tech Research Corporation** in the amount of **$1,404,775** (**$887,974** direct costs + **$516,801** F&A costs).

This Notice of Award (NoA) includes funds for activity with **University of Chicago** in the amount of **$984,000** (**$600,000** direct costs + **$384,000** F&A costs).

This Notice of Award (NoA) includes funds for activity with **St. Jude Children's Research Hospital** in the amount of **$1,364,994** (**$749,997** direct costs + **$614,997** F&A costs).

This Notice of Award (NoA) includes funds for activity with **Weill Medical College of Cornell University** in the amount of **$972,246** (**$573,597** direct costs + **$398,649** F&A costs).

In accordance with the NIAID Financial Management Plan, NIAID does not provide funds for inflationary increases. Committed future year (s) funding was adjusted accordingly. See: https://www.niaid.nih.gov/grants-contracts/financial-management-plan
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This award includes human subject research studies and must conform to the DHHS policies for the Protection of Human Subjects research, which are a term and condition of award. Human subjects research is covered by the 2018 Common Rule, and may not be initiated until the associated protocols have received IRB approval as specified in 45 CFR 46. Failure to comply with the terms and conditions of award may result in the disallowance of costs and/or additional enforcement actions as outlined in Section 8.5 of the NIH Grants Policy Statement.

Awardees who conduct research involving Select Agents (see 42 CFR 73 for the Select Agent list; and 7 CFR 331 and 9 CFR 121 for the relevant animal and plant pathogens at http://www.selectagents.gov/Regulations.html) must complete registration with CDC (or APHIS, depending on the agent) before using NIH funds. No funds can be used for research involving Select Agents if the final registration certificate is denied.

Prior to conducting a restricted experiment with a Select Agent or Toxin, awardees must notify the NIAID and must request and receive approval from CDC or APHIS.

Dissemination of study data will be in accord with the Recipient's accepted genomic data sharing plan as stated in the **Just-In-Time**. Failure to adhere to the sharing plan as mutually agreed upon by the Recipient and the NIAID may result in Enforcement Actions as described in the NIH Grants Policy Statement.

The Research Performance Progress Report (RPPR), Section G.9 (Foreign component), includes reporting requirements for all research performed outside of the United States. Research conducted at the following site(s) must be reported in your RPPR:

BEN-GURION UNIVERSITY OF THE NEGEV, ISRAEL

Duke-NUS Medical School, SINGAPORE

This award is subject to the Clinical Terms of Award referenced in the NIH Guide for Grants and Contracts, July 8, 2002, NOT AI-02-032. These terms and conditions are hereby incorporated by reference, and can be accessed via the following World Wide Web address: https://www.niaid.nih.gov/grants-contracts/niaid-clinical-terms-award All submissions required by the NIAID Clinical Terms of Award must be forwarded electronically or by mail to the responsible NIAID Program Official identified on this Notice of Award.

Select Agents:
Awardee of a project that at any time involves a restricted experiment with a select agent, is responsible for notifying and receiving prior approval from the NIAID. Please be advised that changes in the use of a Select Agent will be considered a change in scope and require NIH awarding office prior approval. The approval is necessary for new select agent experiments as well as changes in on-going experiments that would require change in the biosafety plan and/or biosafety containment level. An approval to conduct a restricted experiment granted to an individual cannot be assumed an approval to other individuals who conduct the same restricted experiment as defined in the Select Agents Regulation 42 CFR Part 73, Section 13.b (http://www.selectagents.gov/Regulations.html).

Highly Pathogenic Agent:
NIAID defines a Highly Pathogenic Agent as an infectious Agent or Toxin that may warrant a biocontainment safety level of BSL3 or higher according to the current edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) (http://www.cdc.gov/OD/ohs/biosfty/bmbl5/bmbl5toc.htm). Research funded under this grant must adhere to the BMBL, including using the BMBL-recommended biocontainment level at a minimum. If your Institutional Biosafety Committee (or equivalent body) or designated institutional biosafety official recommend a higher biocontainment level, the highest recommended containment level must be used. When submitting future Progress Reports indicate at the beginning of the report:

If no research with a Highly Pathogenic Agent or Select Agent has been performed or is planned to be performed under this grant.

If your IBC or equivalent body or official has determined, for example, by conducting a risk assessment, that the work being planned or performed under this grant may be conducted at a biocontainment safety level that is lower than BSL3.

If the work involves Select Agents and/or Highly Pathogenic Agents, also address the following points:

Any changes in the use of the Agent(s) or Toxin(s) including its restricted experiments that have resulted in a change in the required biocontainment level, and any resultant change in location, if applicable, as determined by your IBC or equivalent body or official.

If work with a new or additional Agent(s)/Toxin(s) is proposed in the upcoming project period, provide:

- A list of the new and/or additional Agent(s) that will be studied;
- A description of the work that will be done with the Agent(s), and whether or not the work is a restricted experiment;
- The title and location for each biocontainment resource/facility, including the name of the organization that operates the facility, and the biocontainment level at which the work will be conducted, with documentation of approval by your IBC or equivalent body or official. It is important to note if the work is being done in a new location.

SPREADSHEET SUMMARY
AWARD NUMBER: 1P01AI165077-01 REVISED

INSTITUTION: UNIVERSITY OF WISCONSIN-MADISON

Budget	Year 1
Salaries and Wages	$656,967
Fringe Benefits	$221,196
Personnel Costs (Subtotal)	$878,163
Consultant Services	$60,000
Equipment	$23,942
Materials & Supplies	$311,000
Travel	$59,250
Other	$100,000
Subawards/Consortium/Contractual Costs	$4,726,015
Publication Costs	$12,000
TOTAL FEDERAL DC	$6,170,370
TOTAL FEDERAL F&A	$829,954
TOTAL COST	$7,000,324

Facilities and Administrative Costs	Year 1
F&A Cost Rate 1	55.5%
F&A Cost Base 1	$540,971
F&A Costs 1	$300,239
F&A Cost Rate 2	55.5%
F&A Cost Base 2	$471,971
F&A Costs 2	$261,944
F&A Cost Rate 3	55.5%
F&A Cost Base 3	$482,471
F&A Costs 3	$267,771